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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JUAN MANTELLE and DAVID HOUZE

Appeal 2009-015395
Application 09/986,945
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL[1, 2]

This is an appeal under 35 U.S.C. § 134 involving claims to a transdermal drug delivery system. The Examiner rejected the claims as indefinite, anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

[2] Oral Hearing held January 13, 2011.

Statement of the Case

The Specification teaches that the invention "is directed to a transdermal drug delivery system containing low molecular weight drugs which are liquid at or about room temperatures, its method of making and method of use" (Spec. 1).

The Claims

Claims 1-26 are on appeal. Claims 1 and 19 have been argued separately, but the remaining claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Independent claims 1 and 19 are representative and read as follows:

> 1. A transdermal drug delivery system comprising a blend of:
>
> (a) one or more polymers; and
>
> (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug with a molecular weight of less than about 300 daltons and is liquid at or about room temperatures,
>
> wherein said system is substantially free of water and liquids having a boiling point (i) below processing temperatures and (ii) equal to or greater than the normal boiling points of the at least one low molecular weight drug; and,
>
> wherein at least one of said one or more polymers is a high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit.
>
> 19. A pressure-sensitive adhesive transdermal drug delivery system suitable for transdermal drug delivery comprising a blend of:
>
> (a) a pressure-sensitive adhesive polymer which consists of one or more solvent-based high shear resistant

> acrylic-based polymers having a shear resistance which is greater than or equal to 50 hours at 4 pounds per square inch and 72° Fahrenheit; and
>
> (b) a therapeutically effective amount of one or more drugs, at least one of which is a low molecular weight drug with a molecular weight of less than about 300 daltons and is liquid at or about room temperatures, wherein the transdermal drug delivery system forms a polymer matrix which has sufficient tack and shear to remain in place under conditions of use.

The issues

A. The Examiner rejected claims 1, 5, and 24-26 under 35 U.S.C. § 112, second paragraph as indefinite (Ans. 3).

B. The Examiner rejected claims 1-6, 10-21, 24, and 25 under 35 U.S.C. § 102(b) as anticipated by Miranda[3] (Ans. 3-5).

C. The Examiner rejected claims 1-5, 7, 8, 10, 12, and 14-21 under 35 U.S.C. § 102(b) as anticipated by Pfister[4] (Ans. 5-6).

D. The Examiner rejected claims 1-26 under 35 U.S.C. § 103(a) as obvious over Pfister, Lee,[5] and Horstmann[6] (Ans. 6-8).

A. 35 U.S.C. § 112, second paragraph

The Examiner finds that the "claim recites 'below processing temperatures' the phrase renders the claim unclear because neither the processing temperature nor the active agent is known" (Ans. 3). The Examiner finds that the "claims recite 'equal to or greater than the normal

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[3] Miranda et al., WO 93/00058, published Jan. 7, 1993.
[4] Pfister et al., EP 0524776 A1, published Jan. 27, 1993.
[5] Lee et al., US 5,284,660, issued Feb. 8, 1994.
[6] Horstmann et al., US 5,230,898, issued Jul. 27, 1993.

boiling points of the at least one low molecular weight drug'. The meaning is vague since the drug is not known; there is no way to compare its boiling point to the prior art" (Ans. 3).

Appellants contend, regarding the phrase "below processing temperatures" in claim 1, that a "person skilled in the art making a transdermal drug delivery system readily would know the processing temperatures being used. Thus, this phrase does not refer to an unknown parameter, but one that would be readily known when the invention is practiced" (App. Br. 13). Appellants contend that the "phrase 'equal to or greater than the normal boiling points of the at least one low molecular weight drug' would be understood by a skilled artisan to mean liquids having a boiling point equal to or greater than the normal boiling points of the at least one low molecular weight drug being formulated" (*id.* at 14).

The issues with respect to this rejection are:

(i) Does the evidence of record support the Examiner's conclusion that the phrase "below processing temperatures" in claim 1 is indefinite?

(ii) Does the evidence of record support the Examiner's conclusion that the phrase "equal to or greater than the normal boiling points of the at least one low molecular weight drug" in claim 1 is indefinite?

Findings of Fact

1. The Specification teaches that the "system is substantially free of water and liquids having a normal boiling point (a) optionally below processing temperatures and (b) equal to or greater than (≥) the normal boiling points of the low molecular weight drugs" (Spec. 4).

2. The Specification teaches that "a transdermal drug delivery system which is substantially free of any liquids other than the low molecular weight drug(s) provides for less evaporation of the drug during production of the transdermal device and lower cost due to the simpler composition" (Spec. 10-11).

3. The Specification teaches that

> "liquids having a normal boiling point which is about ≥ the normal boiling points of the one or more drugs" is defined to include enhancers, co-solvents, processing solvents and any other liquid additives which have normal boiling points greater that the boiling point of the low molecular weight drug being used, especially those having boiling points below the processing temperatures.

(Spec. 11.)

4. The Specification teaches that:

> volatile solvents do not include water and generally have a normal boiling point which is less than that of the low molecular weight drug being incorporated into the transdermal system. Volatile solvents include, but are not limited to, alcohols such as isopropanol and ethanol; aromatics such as xylenes and toluene; aliphatics such as hexane, cyclohexane, and heptane; and alkanoic acid esters such as ethyl acetate and butyl acetate.

(Spec. 18.)

Principles of Law

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). "The purpose of claims is not to explain the technology or how it

works, but to state the legal boundaries of the patent grant. A claim is not 'indefinite' simply because it is hard to understand when viewed without benefit of the specification." *S3 Incorporated v. NVIDIA Corp.*, 259 F.3d 1364, 1369 (Fed. Cir. 2001).

Analysis

The Examiner finds that the "claim recites 'below processing temperatures' the phrase renders the claim unclear because neither the processing temperature nor the active agent is known" (Ans. 3).

Appellants contend, regarding the phrase "below processing temperatures" in claim 1, that a "person skilled in the art making a transdermal drug delivery system readily would know the processing temperatures being used. Thus, this phrase does not refer to an unknown parameter, but one that would be readily known when the invention is practiced" (App. Br. 13).

We find that Appellants have the better position. The ordinary artisan practicing the claimed invention would know the processing temperatures being used and would be readily able to identify agents and liquids which would function in accordance with the claim requirements.

The Examiner finds that the "claims recite 'equal to or greater than the normal boiling points of the at least one low molecular weight drug'. The meaning is vague since the drug is not known; there is no way to compare its boiling point to the prior art" (Ans. 3).

Appellants contend that the "phrase 'equal to or greater than the normal boiling points of the at least one low molecular weight drug' would be understood by a skilled artisan to mean liquids having a boiling point

equal to or greater than the normal boiling points of the at least one low molecular weight drug being formulated" (App. Br. 14).

We find that Appellants have the better position. The boiling point of the drug being formulated is readily ascertainable either by access to reference documents or direct measurement. The ordinary artisan would then readily compare the measured or identified boiling point to the other liquids in the system as required by the claim.

Conclusion of Law

(i) The evidence of record does not support the Examiner's conclusion that the phrase "below processing temperatures" in claim 1 is indefinite.

(ii) The evidence of record does not support the Examiner's conclusion that the phrase "equal to or greater than the normal boiling points of the at least one low molecular weight drug" in claim 1 is indefinite.

B. 35 U.S.C. § 102(b) over Miranda

The Examiner finds that "Miranda teaches transdermal drug delivery system and more particularly, to a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition" (Ans. 4). The Examiner finds that "the molecular weight of nicotine is 162.23 g/mol which reads on the instant claims that require the molecular weight of the active agent is lower that 300 Daltons" (*id.*). The Examiner finds that because "the same compounds have same properties, the recitation of 'pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit' is an inherent property to the same compounds of the preparation disclosed by Miranda" (*id.* at 5).

Appellants contend that "Miranda fails to disclose that its acrylic-based polymers are high shear resistant polymers, much less that they have a shear resistance greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" (App. Br. 15). Appellants contend that "the Examiner has failed to identify a single acrylic- based polymer disclosed in Miranda that has the shear resistant characteristics recited in the claims" (*id.*). Appellants contend that "the specific acrylic-based polymers listed in Miranda do not inherently anticipate the polymers recited in the pending claims" (*id.* at 16).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that the polymers of Miranda inherently have "a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" as required by claim 1?

Findings of Fact

5. Miranda teaches "a transdermal drug delivery composition wherein a blend of polymers is utilized to affect the rate of drug delivery from the composition" (Miranda 1, ll. 3-6).

6. Miranda teaches that "active drugs that can be administered by the novel transdermal drug delivery system of this invention include . . . nicotine" (Miranda 20, l. to 21, l. 9).

7. The Examiner finds that "the molecular weight of nicotine is 162.23 g/mol which reads on the instant claims that require the molecular weight of the active agent is lower than 300 daltons" (Ans. 4).

8. Miranda teaches that "the multiple polymer adhesive system comprises a blend of an acrylic pressure-sensitive adhesive and a silicone pressure-sensitive adhesive" (Miranda 15, ll. 22-24).

9. Miranda teaches that "[s]uitable acrylic adhesives are commercially available and include the polyacrylate adhesives sold under the trademarks Duro-Tak 80-1194, Duro-Tak 80-1196, and Duro-Tak 80-1197 by National Starch and Chemical Corporation, Bridgewater, New Jersey" (Miranda 18, ll. 29-33).

10. Miranda teaches that:

> An exemplary general method of preparation is as follows:
>
> 1. Appropriate amounts of polysiloxane and polyacrylate, dissolved in a solvent(s) , are combined and thoroughly mixed together in a vessel.
>
> 2. The drug is then added to the polymer mixture and agitation is carried out until the drug is uniformly mixed in.
>
> 3. Co-solvents and enhancers, if necessary, can then be added to the drug-polymer mixture, and thoroughly mixed.
>
> 4. The formulation is then transferred to a coating operation where it is coated onto a protective release liner at a controlled specified thickness.
>
> 5. The coated product is then passed through an oven in order to drive off all volatile processing solvents.
>
> 6. The dried product on the release liner is then joined to the backing material and wound into rolls for storage.
>
> 7. Appropriate size and shape dosage units are die-cut from the roll material and then pouched.

(Miranda 29, l. 34 to 30, l. 20.)

11. The Specification teaches that "[s]uitable acrylic adhesives are commercially available and include the polyacrylate adhesives sold under

the trademarks Duro-Tak 80-1194, 80-1196, 80-1197, 87-2287, 87-2516 and 87-2852 by National Starch and Chemical Corporation, Bridgewater, New Jersey" (Spec. 13).

12. The Specification teaches that the "pressure-sensitive adhesive according to this embodiment of the present invention generally has a shear resistance of about ≥ 50 hours at 4 psi and 72°F, preferably about ≥ 100 hours at 4 psi and 72°F and more preferably about ≥ 100 hours at 8 psi and 72°F" (Spec. 22).

13. The Specification teaches that:

> In a preferred embodiment, the high shear resistance polymer is a pressure-sensitive acrylic-based adhesive. The term acrylic-based is defined as above. Any acrylic polymer which has a sufficiently high shear resistance can be used in the present invention. A preferred commercially available acrylic polymer is Duro-Tak 87-2852, which has also been described above. Other preferred commercially available acrylic polymers are Gelva Multipolymer Solution 737 and Duro-Tak 87-2194.

(Spec. 23.)

Principles of Law

"[A]nticipation of a claim under § 102 can be found only if the prior art reference discloses every element of the claim …." *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (citing *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1457 (Fed. Cir. 1984)). "[A]bsence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986).

Analysis

Miranda teaches a transdermal drug delivery system which comprises a blend of polymers (FF 5) and a therapeutically effective amount of nicotine, a drug with a molecular weight less than about 300 daltons (FF 6-7). Miranda teaches the use of shear resistant acrylic polymers (FF 8), and specifically teaches that "[s]uitable acrylic adhesives are commercially available and include the polyacrylate adhesives sold under the trademarks Duro-Tak 80-1194, Duro-Tak 80-1196, and Duro-Tak 80-1197 by National Starch and Chemical Corporation, Bridgewater, New Jersey" (Miranda 18, ll. 29-33; FF 9).

Miranda is silent regarding the actual shear resistance of the listed polymers.

Appellants' Specification teaches that "[s]uitable acrylic adhesives are commercially available and include the polyacrylate adhesives sold under the trademarks Duro-Tak 80-1194, 80-1196, 80-1197, 87-2287, 87-2516 and 87-2852 by National Starch and Chemical Corporation, Bridgewater, New Jersey" (Spec. 13; FF 11).

The Examiner reasonably finds that "the prior art clearly used the same polymers in the same invention (polyacrylates in transdermal composition)" (Ans. 9). We think the Examiner has reasonably established a prima facie case of inherency based upon the identity of the Duro-Tak 80-1194, Duro-Tak 1196, and Duro-Tak 80-1197 polymers between Miranda and Appellants' Specification. *See In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990) ("[W]hen the PTO shows sound basis for believing that the products

of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.")

Appellants contend that "Miranda fails to disclose that its acrylic-based polymers are high shear resistant polymers, much less that they have a shear resistance greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" (App. Br. 15).

We are not persuaded. In the instant case, the polymers of Miranda and the Specification are identical. The Examiner has reasonably shifted the burden to Appellants to demonstrate that Miranda's polymers do not have the characteristics recited in the claims. *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) ("Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.")

Appellants contend that the

> data sheets in the evidence appendix show that both Duro-Tak 80-1194 and Duro- Tak 80-1196 have a shear resistance of only 15 hours at 8 pounds per square inch and 72° Fahrenheit, and Duro-Tak 80-1197 has a shear resistance of >24 hours at 4 pounds per square inch and 72° Fahrenheit. *See* Duro-Tak 87-2194 Data Sheet (for Duro-Tak 80-1194, since renamed 87-2194); Duro-Tak 87-2196 Data Sheet (for Duro-Tak 80-1196, since renamed 87- 2196); and Duro-Tak 80-1057 Data Sheet (for Duro-Tak 80-1197, now discontinued but in the same family as Duro-Tak 80-1057) (copies attached). Thus, the specific acrylic-based polymers listed in Miranda do not inherently anticipate the polymers recited in the pending claims.

(App. Br. 15-16.)

We are not persuaded. We have reviewed Appellants' data sheet evidence submitted on March 18, 2008, but this evidence relates to three acrylic polymers which are different than those listed in Miranda and the evidence is not in the form of a Declaration. The documents are not self proving, in the sense that there is no statement in the Duro-Tak 87-2194 Data sheet that it ever had a different name. Also, we cannot review Appellants' characterization of these references that, for example, Duro-Tak 80-1194 was renamed 87-2194, because this characterization is not evidence, but rather represents attorney argument. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

In addition, the internal evidence of Appellants' Specification does not support this position, since the Specification mentions Duro-Tak 80-1194 at page 13 and also mentions Duro-Tak 87-2194 at page 23, without ever mentioning that these are the same material (FF 11, 13).

Therefore, without rebuttal evidence such as data sheets which properly name the three specific Duro-Tak compounds disclosed by Miranda and the Specification as suitable acrylic adhesives, we agree with the Examiner that the burden is properly placed on Appellants to demonstrate that the identical adhesives will not satisfy the requirements of the claims.

Conclusion of Law

The evidence of record supports the Examiner's finding that the polymers of Miranda inherently have "a shear resistance which is greater

than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" as required by claim 1.

C. 35 U.S.C. § 102(b) over Pfister

The Examiner finds that "Pfister teaches a silicone pressure sensitive adhesive composition, which is compatible with drugs, excipients, co-solvents and skin penetration enhancers is disclosed which includes a cohesive strengthening agent. The adhesive is useful as a transdermal drug delivery device" (Ans. 5). The Examiner finds that Pfister teaches a "blend of polymers are used in the invention like siloxane polymers (page 3, line 10+), and acrylic acid polymers of high shear resistance that has molecular weights from about 1,000,000 to about 4,000,000" (*id.*). The Examiner finds that "since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping" (*id.*).

Appellants contend that "Page 14 of Pfister describes the shear of the entire adhesive composition, which includes the silicone pressure sensitive adhesive and a cohesive strengthening agent. Pfister does not describe the shear resistance of the individual polymers, let alone that of the acrylic carbomer" (App. Br. 17). Appellants contend that therefore "Pfister does not teach a composition comprising an acrylic-based polymer with a shear resistance of 50 hours at 8 pounds per square inch at 72° Fahrenheit or 50 hours at 4 pounds per square inch at 72° Fahrenheit" (*id.*).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's finding that the acrylic carbomers of Pfister

inherently have "a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" as required by claim 1?

Findings of Fact

14. Pfister teaches that in

> transdermal drug delivery patches, ingredients such as co-solvents and excipients have been added to the silicone pressure sensitive adhesive compositions to improve efficacy. Co-solvents are typically added to increase drug solubility in the composition and excipients are typically added to enhance drug release from or through the composition

(Pfister 2, ll. 12-15).

15. Pfister teaches a "cohesive strengthening agent thought to be useful is carboxypolymethylene is also known as 'carbomer'. Generally, it is a cross linked polymer of acrylic acid having 0.75-2.0 weight percent polyalkylsucrose . . . with molecular weights from 1×10^6 to 4×10^6" (Pfister 5, ll. 25-28).

16. Pfister teaches "drugs such as nicotine-based drugs" (Pfister 1, l. 17).

17. The Examiner finds that "since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping" (Ans. 5).

Principles of Law

In general, a limitation is inherent if it is the "'natural result flowing from'" the explicit disclosure of the prior art. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). "Inherency … may not be established by probabilities or possibilities. The mere fact that a certain

thing *may* result from a given set of circumstances is not sufficient." *MEHL/Biophile Int'l. Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) (quoting *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)).

Analysis

Pfister teaches transdermal patches with acrylic adhesives which may include drugs such as nicotine (FF 14-16). The Examiner finds that "since the ranges of the molecular weight of the acrylic polymers overlap at the 1,000,000 value then it is expected that the shear resistance values should be overlapping" (Ans. 5; FF 17).

We are not persuaded. Unlike the situation with Miranda, where the same acrylic polymers would be expected to have identical properties, the Examiner has not provided any evidence that simply because the molecular weights of the acrylic polymers overlap, they would be expected to have identical shear resistance properties. The Examiner does not identify any acrylic polymer in Pfister which satisfies the claim requirement for "a high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" (Claim 1).

We have reviewed table C2 of Pfister, which is cited by the Examiner, but this table does not use acrylic polymers, only silicone adhesives and calcium stearate, and also does not demonstrate that the tapes satisfied the shear requirements of the claim.

Conclusion of Law

The evidence of record does not support the Examiner's finding that the acrylic carbomers of Pfister inherently have "a shear resistance which is

greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" as required by claim 1.

D. *35 U.S.C. § 103(a) over Pfister, Lee, and Horstmann*

Having reversed the anticipation rejections over Pfister for the absence of a teaching of "a high shear resistant acrylic-based pressure-sensitive adhesive polymer having a shear resistance which is greater than or equal to 50 hours at 8 pounds per square inch and 72° Fahrenheit" (Claim 1), we necessarily reverse the obviousness rejection as the Lee and Horstmann references are not relied upon by the Examiner to address this limitation.

SUMMARY

In summary, we reverse the rejection of claims 1, 5, and 24-26 under 35 U.S.C. § 112, second paragraph as indefinite.

We affirm the rejection of claims 1-6, 10-21, 24, and 25 under 35 U.S.C. § 102(b) as anticipated by Miranda.

We reverse the rejection of claims 1-5, 7, 8, 10, 12, and 14-21 under 35 U.S.C. § 102(b) as anticipated by Pfister.

We reverse the rejection of claims 1-26 under 35 U.S.C. § 103(a) as obvious over Pfister, Lee, and Horstmann.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

cdc

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